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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/944,884 | 08/31/2001 | Kevin P. Baker | P2548P1C15 | 5993 |

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EXAMINER

LI, RUIXIANG

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1646

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/944,884 | BAKER ET AL. | |
| | Examiner | Art Unit | |
| | Ruixiang Li | 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 and 32-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-29, 32-34 and 38-41 is/are allowed.
- 6) ☒ Claim(s) 35-37, 42, and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11/14/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed on November 14, 2003 has been entered in full. Claims 22-24, 30, and 31 have been canceled. Claims 25-29, 32-41 have been amended. Claims 42 and 43 have been added. Claims 25-29 and 32-43 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Information Disclosure Statement

The information disclosure statement filed on November 14, 2003 has been considered by the Examiner.

III. Withdrawn Objections and/or Rejections

Applicants' cancellation of claims 22-24, 30, and 31 has made all the rejections set forth in the record (Paper No. 9, August 11, 2003) moot.

The rejection of claims 25-29, 32-34, and 38-41 under 35 U.S.C. 112, first paragraph for scope of enablement, as set forth at pages 4-6 of the previous Office Action (Paper No. 9, August 11, 2003), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 25-29, 32-34, and 38-41 under 35 U.S.C. 112, first paragraph for written description, as set forth at pages 7-9 of the previous Office Action (Paper No. 9, August 11, 2003), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 25-27, 36, and 38-41 under 35 U.S.C. 112, second paragraph, as set forth at pages 9-10 of the previous Office Action (Paper No. 9, August 11, 2003), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claim 37 under 35 U. S. C. § 102 (b) as being anticipated by Dreher et al. (GENEMBL, Accession No. U17834, January 5, 1995), as set forth at pages 10-11 of the previous Office Action (Paper No. 9, August 11, 2003), has been withdrawn in view of Applicants' amendment to the claims.

The objection to claims 28, 29, and 32-34, as set forth at page 11 of the previous Office Action (Paper No. 9, August 11, 2003), has been withdrawn in view of Applicants' amendment to the claims.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Scope of Enablement)

The rejection of claims 35-37 under 35 U. S. C. § 112, 1st paragraph, as set forth at pages 4-6 of the previous Office Action (Paper No. 9, August 11, 2003), remains.

The newly added claim 42 is also rejected under 35 U. S. C. § 112, 1st paragraph for scope enablement. The basis for the rejection is as set forth at pages 4-6 of the previous Office Action (Paper No. 9, August 11, 2003).

At the second paragraph of page 12 of Applicants' response, Applicants argue that Applicants have amended claim 35 to reflect that the hybridization of the nucleic

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acid occurs under high stringency conditions. Amended claim 36 sets forth specific high stringency conditions. Amended claim 37 reflects the claimed polynucleotides must be at least 35 nucleotides in length. The hybridization reaction under the claimed conditions is well-known in the art. Therefore, the amended claims 35-37 overcome the rejection.

Applicants' argument has been fully considered but is not deemed to be persuasive for the following reasons. The claims, while amended by addition of a limitation of hybridization under high stringency conditions, are still remarkably broad and encompass a genus of nucleic acids that vary substantially both in length and in nucleotide composition. For instance, the claims encompass a nucleic acid comprising a fragment of the nucleic acid encoding SEQ ID NO: 2, a variant of the nucleic acid sequence encoding SEQ ID NO: 2 (including the nucleic acid sequence of SEQ ID NO: 1), and a genomic DNA sequence that encode the amino acid sequence of SEQ ID NO: 2. However, the specification fails to provide sufficient guidance or working examples on how to make and/or use such an enormous genus of nucleic acid. For example, the specification fails to teach an artisan how to use the variants of the nucleic acid encoding SEQ ID NO: 2 (including the nucleic acid sequence of SEQ ID NO: 1) that do not possess the same activity as that of the nucleic acid encoding the amino acid of SEQ ID NO: 2. The specification fails to teach an artisan how to make a genomic DNA sequence that encodes the amino acid sequence of SEQ ID NO: 2 and hybridizes under high stringency condition to the nucleic acid encoding SEQ ID NO: 2. There are no teachings in the prior art on how to use those variants that do not have the same activity as that of nucleic acid sequence encoding SEQ ID NO: 2 or how to make the genomic

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DNA sequence that might hybridize to the nucleic acid encoding SEQ ID NO: 2. It is unpredictable whether a nucleic acid molecule that hybridizes to the nucleic acid encoding SEQ ID NO: 2 possesses the same function or activity as that of the nucleic acid encoding SEQ ID NO: 2. Thus, it would require undue experimentation for an artisan to make and/or use the invention commensurate in scope with the claims.

Claim 42 recites an isolated nucleic acid comprising a sequence that encodes a polypeptide of SEQ ID NO: 2 with conservative amino acid substitutions, wherein the polypeptide stimulates release of proteoglycans from cartilage. Even with the functional limitation, the claim still encompasses an enormous genus comprising nucleic acids encoding homologues of SEQ ID NO: 2. In fact, each and every amino acid residues could be potentially substituted. However, the specification fails to teach how to make such a huge number of homologues of SEQ ID NO: 2. Thus, it would require undue experimentation for an artisan to make the nucleic acids that encode these homologues of SEQ ID NO: 1. An acceptable percent amino acid/or nucleic acid sequence identity is required to overcome the rejection of claim 42.

V Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Written Description)

The rejection of claims 35-37 under 35 U. S. C. § 112, 1st paragraph for written description, as set forth at pages 7-9 of the previous Office Action (Paper No. 9, August 11, 2003), remains.

The newly added claim 42 is also rejected under 35 U. S. C. § 112, 1st paragraph for written description. The basis for the rejection is as set forth at pages 7-9 of the previous Office Action (Paper No. 9, August 11, 2003).

At the third paragraph of page 19 of Applicants' response, Applicants argue that claim 35 has been amended to specify hybridization under "high stringency conditions" and claim 36 has been amended to specify an exemplary set of conditions for "high stringency", whereas claim 37 has been amended to require hybridization of a polynucleotide which is at least 35 nucleotides in length, thereby increasing the hybridization specificity. Applicants further submit that Applicants have fully disclosed a representative of the claimed genus and have described the methods for deriving the claimed species.

This has been fully considered but is not deemed to be persuasive for the following reasons. First, the amended claims still encompass an enormous genus of nucleic acids that vary substantially both in length and in nucleotide composition. As noted in the previous office action, the claims do not require that the nucleic acid possesses any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. The claims read on, for example, a nucleic acid comprising a fragment of the nucleic acid encoding SEQ ID NO: 2, a variant of the nucleic acid sequence that do not have the same activity as that of the nucleic acid encoding the SEQ ID NO: 2, and even a genomic DNA sequence that encode the amino acid sequence of SEQ ID NO: 2. Secondly, the specification only discloses the cDNA sequence of SEQ ID NO: 1 and the amino acid sequence of SEQ ID NO: 2 encoded by SEQ ID NO: 1 (Figures 1-2 of the specification). The specification fails to provide a reasonable number of representative species of the claimed genus. For example, the specification does not provide any description for the variants of the nucleic acid encoding the amino acid sequence of SEQ ID NIO: 2 that do not have the

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same activity as that of the nucleic acid encoding the amino acid sequence of SEQ ID NO: 2 or any genomic DNA sequence that hybridize to the nucleic acid encoding SEQ ID NO: 2. Furthermore, adequate written description requires more than reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim 42 recites an isolated nucleic acid comprising a sequence that encodes a polypeptide of SEQ ID NO: 2 with conservative amino acid substitutions, wherein the polypeptide stimulates release of proteoglycans from cartilage. Despite that the claim has a functional limitation, the claim still encompasses a genus of nucleic acids encoding a huge number of homologues of SEQ ID NO: 2. The specification fails to provide representative species of the claimed genus. The prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed nucleic acid molecules as being identical to those instantly claimed. Therefore, due to the breadth of the claim genus and lack of the definitive structural features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

VI. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph, New Matter

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. Claim 43 recites “an isolated nucleic acid comprising a sequence that encodes a polypeptide of SEQ ID NO: 2 with 0-10 amino acid additions, deletions, or substitutions, ...”. However, there is no support for the limitation of “0-10 amino acid additions, deletions, or substitutions” in the specification.

VII. Claim Rejections Under 35 USC § 112, 2nd paragraph

Amended claims 35 and 37 are rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 is indefinite because it recites “under high stringent conditions”, without defining the hybridization conditions in the claims. Since neither the art nor the specification provides an unambiguous definition for the terms, the claim is indefinite. Claim 37 depends from claim 35.

Applicants argue that Applicants define “stringent conditions” or “high stringency conditions” on page 30 of the specification, and provide exemplary hybridization and wash conditions as part of this definition. Applicants’ argument has been fully considered, but is not deemed to be persuasive because the specification on page 30 only provides exemplary conditions for “high stringency conditions” (Note the use of “for example” at page 30 of specification). Since neither the art nor the specification provides an unambiguous definition for the term, the claims are indefinite.

VIII. Claim Rejections Under 35 USC § 102 (b)

The rejection of claims 35 and 36 under 35 U. S. C. § 102 (b) as being anticipated by Dreher et al. (GENEMBL, Accession No. U17834, January 5, 1995), as set forth at pages 10-11 of the previous Office Action (Paper No. 9, August 11, 2003), remains.

Applicants argue that the teachings in the reference of Dreher et al. fall out of amended claims 35 and 36. The 24 nucleotide sequence from the Dreher et al., which is located at the end of 3' coding region of the PRO241 DNA, would be unable to hybridize to the nucleic acid sequence encoding SEQ ID NO: 2 under high stringency conditions. Applicants' argument has been fully considered, but is not deemed to be persuasive because the nucleotide sequence taught by Dreher et al. comprises 24 consecutive nucleotides that encode 8 amino acids of SEQ ID NO: 2 and its complementary sequence would hybridize to the nucleic acid sequence encoding the polypeptide of SEQ ID NO: 2. It is well known in the art that a short nucleotide sequence (e.g., a nucleic acid probe) can hybridize, under high stringency conditions, to a long nucleotide sequence that encodes a protein. In addition, the claims do not have a length limitation and do not specify the region that a nucleic acid hybridizes to.

IX. Conclusion

Claims 25-29, 32-34, and 38-41 are allowed. Claims 35-37, 42, and 43 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record

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includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Ruixiang Li
Examiner
January 28, 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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